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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/068,293	05/06/1998	ZIV SANDALON	AEM96-01A	2169
7590	03/31/2004		EXAMINER	
John P. White COOPER & DUNHAM 1185 Avenue of the Americas New York, NY 10036			GUZO, DAVID	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 03/31/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

8/11

**Advisory Action**

**Application No.**

09/068,293

**Applicant(s)**

SANDALON ET AL.

**Examiner**

David Guzo

**Art Unit**

1636

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 15 March 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: 29-34 and 47.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1,2,4-13,16-20,22-28,35-37,41-43,45 and 46.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☒ Other: See Continuation Sheet

  
DAVID GUZO  
PRIMARY EXAMINER

Continuation of 5. does NOT place the application in condition for allowance because: Applicants reiterate that page 34 of the specification teaches that in vitro packaging of nucleic acids in SV40 does not involve nucleoprotein formation. Applicants point to passages that recite the following: (1) in vitro packaging using naked DNA, prepared in *E. coli*; (2) LCR elements that do not interfere with in vitro packaging but only form higher order complexes in vivo and (3) that the use of supercoiled DNA in vitro is predicted to relieve packaging problems encountered in vivo by formation of nucleoproteins. Initially, it is noted that the specification does not provide explicit support for the claimed language. The section of the specification cited by applicants does not support the amended claims because it only recites packaging of "supercoiled DNA" in vitro which is predicted to relieve packaging problems in vitro created by formation of nucleoproteins and that LCR elements do not interfere with in vitro packaging because these LCR elements only form "higher order nucleoprotein structures" in vivo. While the specification does recite "...in vitro packaging utilizes naked DNA, prepared in *E. coli*...", this limitation does not provide support for claims which recite any "recombinant nucleic acid" constituent (claim 18, this reads on DNA, RNA, etc.) or antisense RNA, ribozyme RNA, purified exogenous RNA, etc.(claims 1 and 35) as the nucleic acid constituents because the specification does not teach these constituents (RNA, ribozymes, antisense molecules etc.) in the context of their not being nucleoproteins. In summary, the only non-nucleoprotein which the specification provides support for involves "naked DNA, prepared in *E. coli*".

Continuation of 10. Other: The examiner notes that in the previous Office Action, the examiner neglected to note that claim 47 was also allowed. .